K011328

NOV 21 2001

BIONET CO., LTD.
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SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

COMPANY:	Bionet Co., LTD 3F, Daeyang Bldg., 999 Daechi-Dong, Kangnam-gu Seoul, South Korea
CONTACT:	Dong-Joo Kang President Tel: +82-2-3468-3645 Fax: +82-2-3468-3699
TRADE NAME:	Cardio Care EKG-2000
COMMON NAME:	12-Channel Electrocardiograph
CLASSIFICATION NAME:	Electrocardiograph
PRODUCT CODE:	74 LOS
REVIEW PANEL:	Division of Cardiovascular and Respiratory Devices
PERFORMANCE STANDARD:	EKG-2000 meets all design specifications and is substantially equivalent to the predicate device. The device is designed to meet UL Standard 2601, IEC 601-1-2 CSA 22.2 standards for electrical safety for medical equipment to prevent the possible of excessive electrical leakage amount to the patient. In addition, testing was performed to demonstrate compliance with ANSI/AAMI EC11-1991, "Diagnostic Electrocardiographic Devices." A hazard analysis of the system and its software was performed.

SUBSTANTIAL EQUIVALENCE:

The EKG-2000 System is substantially equivalent to the Fukuda Denshi Model FCP-4101, 510(k) number 913811.

DEVICE DESCRIPTION:

The EKG-2000 Electrocardiograph is intended to be used for the evaluation of the cardiovascular system. It acquires, records, and prints 12 channel electrocardiographic waveform. it features 12 leads simultaneous 10-second resting EKG with interpretation. This ECG is designed to produce a thermally printed recording of the electrical signals produced by the heart. Patient information and user identification are printed along with ECG on the output report is effective for hospital chart control. It has a RS 232C communication port and an Ethernet port.

INDICATIONS FOR USE:

The EKG-2000 Cardio Care is intended to be used under the direct supervision of a licensed healthcare practitioner. The EKG-2000 is intended to be used by trained operators in the hospital or medical professional's facility environment to record ECG signals from surface electrodes. The device is intended to acquire, analyze, display, and record electrocardiographic information from adult population. The device is not intended for home use. The device is not intended for pediatric population.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Min Soo Han
BIONET CO., LTD.
3F, Daeyang Bldg. 999
Daechi-Dong, Kangnam-Gu
Seoul
KOREA

Re: K011328
Trade Name: Cardio Care EKG-2000 12-Channel Electrocardiograph
Regulation Number: Not Available
Regulation Name: Not Available
Regulatory Class: Unclassified
Product Code: 74 LOS
Dated: August 22, 2001
Received: August 24, 2001

Dear Mr. Han:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011328

INDICATIONS FOR USE STATEMENT

Device Name

EKG-2000 Cardio Care

Indications for Use

The EKG-2000 Cardio Care is intended to be used under the direct supervision of a licensed healthcare practitioner. The EKG-2000 is intended to be used by trained operators in a hospital or medical professional's facility environment to record ECG signals from surface electrodes. The device is intended to acquire, analyze, display, and record electrocardiographic information from adult population. The device is not intended for home use. The device is not designed for intracardial use.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011328